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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ARNOLD & PORTER
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555 12TH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	27

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/267,199	BHAT ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18,20-22 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18,20-22 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

All rejections and objections not repeated below are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. 101/112 Utility Rejections

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-18, 20-22, and 25 are again rejected, as previously set forth and maintained in the office actions of 6/5/01, 4/10/02, and 1/2/03, under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or by a well established utility.

Applicant's arguments filed 4/2/03 have been fully considered but they are not persuasive.

In response to the argument that the claimed nucleic acids are useful for determining the presence or absence of polymorphisms, or for acting as hybridization probes, in gene mapping, for isolation of homologous sequences, detection of gene expression, as molecular weight markers, and for "numerous other genetic engineering uses", the examiner maintains that these are general uses (purposes) applicable to the general class of nucleic acids and are not specific to the SEQ ID NO's claimed. It is well known in the art that polynucleotides, including others than those recited in the instant claims, can be used in hybridization assays to obtain other (e.g. homologous or complementary) nucleic acid sequences, to identify polymorphisms, etc. A nucleic acid molecule may have utility based on its use as a marker or probe for or related to a specific disease condition (e.g. probes for Huntington's chorea, cystic fibrosis, etc.); however, no correlation between a claimed SEQ ID NO: and a specific disease condition is taught by the instant specification. Similarly, a "use" for gene mapping or a chromosome "walk" requires that a correlation between a claimed nucleic acid sequence and a particular gene or chromosome be known. No correlation between an inventive sequence and a gene or chromosome is disclosed by the instant specification. A "use" to map a particular nucleic acid to a gene or chromosome is considered a "use" to do further research. A use as a marker is a generic use, and is not

specific to any of the claimed sequences. A "use" for expression profiling requires knowledge of a time (e.g. developmental stage) and/or "place" (e.g. tissue) of expression, and knowledge of what a normal or abnormal level of expression is for the claimed nucleic acid. In the absence of such knowledge, the "use" of the claimed nucleic acid would be that of further research; i.e. to obtain information regarding expression (or lack thereof) in particular tissues and/or specific developmental stages. Applicant is reminded that a "use" to do further research is not a specific, substantial and credible utility under 35 USC 101. Isolation of a homologous sequence, wherein a utility for either the homologous sequence or the isolating sequence is not known, does not confer utility on the isolating sequence. Applicant equates use of his sequences to use of monoclonal antibodies for isolation of cells in flow sorting; however, it is noted that antibodies, in general, have utility under 35 USC 101 due to their unique properties (in recognizing/binding to specific epitopes). Nucleic acids, in general, do not have utility based on recognized unique properties, therefore the comparison is not persuasive. Applicants further argue that as their nucleic acids encode enzymes of the tocopherol pathway, they can be used to modulate the tocopherol content and/or vitamin E content of plant tissues. In response, it is noted that the specification does not disclose that any of the claimed nucleic acid sequences is actually known to encode an enzyme of the tocopherol pathway, as set forth below. Further, it is not known or disclosed whether any of the claimed nucleic acid sequences is known to be involved in *modulation* of tocopherol or vitamin E synthesis.

In the instant case, it is asserted that the claimed nucleic acid molecules encode tocopherol synthesis pathway enzymes or fragments thereof. Each nucleic acid molecule claimed has at least one (and in most cases, several) ATG "codons". However, it is not known for ANY of the claimed sequences what the ORF is, therefore it is unknown whether any sequence is actually translated into a peptide, or, if translated, what the activity or function of that peptide may be. For example, SEQ ID NO: 180 comprises four "ATG' codons, but it is not known which, if any, is the start codon for a tocopherol synthesis pathway enzyme.

As previously set forth, homology alone is not evidence that a particular protein is indeed encoded by a recited nucleic acid sequence. See p. 7 of the office action of 11/21/00 regarding lack of predictability based on sequence homology. The prior art does not teach that the elected SEQ ID's encode the alleged proteins and the specification does not show that the peptides putatively encoded by the claimed nucleic acid sequences have an activity or function similar to those to which they are homologous.

As the instant specification does not disclose, and the prior art does not teach, that the instantly claimed nucleic acid sequences actually encode any protein or peptide, specifically the enzymes recited in Table A, the nucleic acid sequences represented by SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 199, and 232 do not have utility based on utility of a protein encoded thereby.

For all of the reasons previously set forth and set forth above, the rejection is maintained.

Claims 10-18, 20-22, and 25 are also rejected under 35 U.S.C. 112, first paragraph for not being enabled.

Applicant's arguments have been fully considered but they are not persuasive. This enablement rejection is linked to the utility rejection, as previously set forth. As the utility rejection is maintained, the enablement rejection is also maintained.

Claim Rejections - 35 USC § 112, 1rst paragraph

Claims 10-18 and 20-22 are again rejected, as previously set forth in the office action of 1/2/03, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

Applicant's arguments filed 4/2/03 have been fully considered but they are not persuasive.

Applicants argue that the claimed nucleic acid sequences/structures are described by the specification; this is not in dispute. It is noted that claim 25, which recites an isolated nucleic acid consisting of SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232 is not rejected herein. Applicant further argues, in summary, that the claims may be broader than a specific embodiment disclosed, that the specification need not particularly describe every embodiment encompassed by a claim, and that the specification does describe possible variants of the claimed SEQ ID NO's and that common structural features have been described for the claimed nucleic acids. In response, it is noted that while the claims may indeed be broader than specific embodiments disclosed in the specification, the description must still be sufficient to permit one

skilled in the art to immediately envisage the product claimed. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species). In the instant case, the claims encompass sequences comprising introns, noncoding regions, and regions which do not hybridize to the claimed sequences, but which may still meet the claimed limitations, as set forth above. These sequences are not described by the instant specification and one skilled in the art would not be able to immediately envisage these products or structures. Applicant argues that every structure embodies by the claims necessarily includes a common structural feature; i.e. one of the claimed nucleic acid sequences, this statement; however, this is not true for claims reciting hybridization limitations. It is known in the art that sequences (e.g. genes) may comprise introns and noncoding regions which do not complement a particular length of a comparative sequence, but the two sequences are still able to hybridize wherein the noncomplementary regions "bubble out." It is therefore entirely possible for a longer sequence to comprise portions which complement, and therefore hybridize to, a claimed SEQ ID NO: wherein the hybridizing sequence does not comprise a claimed SEQ ID NO.

For these reasons and those previously set forth, the rejection is maintained.

Conclusion

Claims 10-18, 20-22 and 25 are again rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

/Marjorie A. Moran/

MARJORIE MORAN
PATENT EXAMINER

mam
June 14, 2003